K 122951

510(k) Summary

JAN 17 2013

510(k) OWNER:

iCAD Inc.
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Nashua, NH 03062
T: 603-882-5200 Ext 7945
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Registered Establishment Number: 1225671

MANUFACTURER FACILITY:

Xoft Inc. a Subsidiary of iCAD Inc.
101 Nicholson Lane
San Jose, CA 94134
Registered Establishment Number: 3005594788

NAME OF CONTACT:

John A. DeLucia
VP, Regulatory Affairs, Clinical Affairs and Quality Assurance

DATE SUMMARY PREPARED: December 12, 2012

TRADE NAME: Xoft Electronic Brachytherapy System

COMMON NAME: Radiation Therapy System

CLASSIFICATION: Class II

CLASSIFICATION NAME: X-Ray Radiation Therapy System

CRF CLASSIFICATION: 21 CFR 892.5900

PRODUCT CODE: JAD

SECTION 6: 510(K) Summary (con't)

Legally Marketed Devices to Which Substantial Equivalence is Claimed

The Axxent Electronic Brachytherapy System Controller is substantially equivalent to the following legally marketed predicate devices. When used with applicators or sources both devices treat lesions, tumors and conditions in or on the body where radiation is indicated.

Device Name	Manufacturer	510(k) Reference #	Concurrence Date
Axxent Electronic Brachytherapy System	Xoft	K072683	2/29/08
VariSource 200 HDR Afterloader	Varian	K061582	7/25/06

Device Description

The Axxent Electronic Brachytherapy System consists of three primary components: the Axxent System Controller (Controller); the Axxent HDR X-ray Source-2.2 (Source); and an Axxent-compatible applicator (Applicator). The System is designed to deliver doses of X-ray radiation to the tissue in proximity to the applicator using a disposable, miniature X-ray tube powered by the Controller.

The Axxent Electronic Brachytherapy Controller is a mobile, computer-controlled platform that is responsible for the overall operation of the System. The Controller is designed to work with the Source, which is a disposable, miniature X-ray tube located at the end of a flexible cable. The Source is inserted into a lumen of the appropriate Applicator.

Intended Use / "Indications for Use"

The Axxent® Electronic Brachytherapy System is a high dose rate Brachytherapy device for use with Axxent Applicators to treat lesions, tumors and conditions in or on the body where radiation is indicated.

⚠ WARNING

The safety and effectiveness of the Axxent Electronic Brachytherapy System as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

Summary of Technological Characteristics

The technological characteristics of the Axxent Electronic Brachytherapy System Controller are the same as the Axxent Electronic Brachytherapy System cleared in K072683, and are similar to the Varian VariSource 200 HDR Afterloader cleared under K061582. These devices are equivalent in terms of design, materials, principles of operation, and product specifications.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management is ensured via a risk analysis which is used to identify potential hazards. Any potential hazards are controlled via software development, verification and validation testing.

Assessment of Non-Clinical Performance Data

Validation testing was performed according to a Software System Test Plan. All performance, functional and system requirements were met.

Conclusion

This traditional 510(k) for the Axxent® Electronic Brachytherapy System Controller contains adequate information and data to determine substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mr. John DeLucia
VP, RA/QA/CA
iCAD, Inc.
98 Spitbrook Rad
NASHUA NH 03062

January 17, 2013

Re: K122951
Trade/Device Name: Axxent(R) Electronic Brachytherapy System
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: December 12, 2013
Received: December 13, 2013

Dear Mr. DeLucia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122951

Device Name: Axxent® Electronic Brachytherapy System

Indications for Use: The Axxent® Electronic Brachytherapy System is a high dose rate brachytherapy device for use with Axxent Applicators to treat lesions, tumors and conditions in or on the body where radiation is indicated.

WARNING

The safety and effectiveness of the Axxent Electronic Brachytherapy System as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

Prescription Use __X__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health
510(k)_____**K122951**_____